

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION**

PDL BioPharma, Inc.,

Plaintiff,

v.

Eli Lilly and Company,

Defendant.

Civil Action No. 23-2289-RLY-MKK

**DEMAND FOR JURY TRIAL**

**REVISED [PROPOSED] CASE MANAGEMENT PLAN**

On March 20, 2024, the parties tendered their Case Management Plan (the “CMP”). ECF No. 39. In the CMP, the parties agreed to stay discovery in this matter until (1) donanemab receives FDA approval or (2) the Court denies Lilly’s motion to dismiss. *Id.* at 4. The parties proposed schedule was keyed off FDA approval of donanemab (referred to as the “Trigger Date”). The Court exercised its discretion to stay discovery until August 30, 2024, and ordered the parties to file a joint status report within seven days of FDA approval for donanemab. ECF No. 55 at 2. On July 2, 2024, donanemab received FDA approval. The parties filed a joint status report, notifying the Court of donanemab’s FDA approval on July 9, 2024, and submitting that the Trigger Date under the CMP should be July 2, 2024. ECF No. 58. On July 11, 2024, the Court lifted the stay of discovery and ordered the parties to submit a revised CMP with specific dates. ECF No. 59. Accordingly, the parties hereby tender this revised CMP.

**I. Parties and Representatives**

A. **Plaintiff:** PDL BioPharma, Inc. (“PDL” or “Plaintiff”)

**Defendant:** Eli Lilly and Company (“Lilly” or “Defendant”)

B.

Counsel for Plaintiff	Counsel for Defendant
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Counsel shall promptly file a notice with the Clerk if there is any change in this information.

## **II. Jurisdiction and Statement of Claims**

- A. The parties shall state the basis for subject matter jurisdiction. If there is disagreement, each party shall state its position.

PDL is a corporation and a citizen of the States of Delaware and Nevada. Lilly is a corporation and a citizen of the State of Indiana. This Court has subject matter jurisdiction under 28 U.S.C. § 1332 because there is complete diversity of citizenship and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs. Venue is proper in this judicial district under 28 U.S.C. § 1391.

In its Memorandum of Law in Support of its Motion to Dismiss (ECF No. 36), Lilly contended that PDL lacks Article III standing because the product at issue—donanemab—has not yet been approved by the FDA and Lilly had not started selling donanemab. Given donanemab was approved by the FDA on July 2, 2024 (ECF No. 58), Lilly withdraws this challenge to the Court’s subject matter jurisdiction.

### **B. Plaintiff’s Statement of Claims**

This is a case for anticipatory breach of contract and declaratory relief pursuant to 28 U.S.C. § 2201(a). Specifically, PDL asserts that Lilly’s donanemab is a Licensed Product that incorporates PDL Technical Information under the Development and License Agreement between the parties (the “Agreement”). Although donanemab is a “Licensed Product” that incorporates “PDL Technical Information” under the Agreement, Lilly has unequivocally repudiated its obligation to pay royalties to PDL on sales of donanemab once it receives FDA approval. In doing so, Lilly has anticipatorily breached the parties’ license agreement, thereby entitling PDL to a declaratory judgment that Lilly owes royalties to PDL on sales of donanemab under the plain terms of the Agreement. In its Memorandum of Law in Support of its Motion to Dismiss (ECF No. 36), Lilly contends that the complaint does not adequately allege that donanemab is a Licensed Product that incorporates “PDL Technical Information” under the Agreement. First, the complaint alleges that donanemab is a Licensed Product because it “incorporates substantially all of the variable light chain region of one or more of the antibodies humanized by PDL for Lilly.” ECF No. 1 at ¶ 28. Second, the complaint alleges that Lilly used PDL’s process to humanize donanemab and

that donanemab thus incorporates “PDL Technical Information.” *Id.* at ¶¶ 29-30. Lilly also contends that PDL’s anticipatory breach claim cannot depend on its good-faith disagreement about the application of disputed contractual provisions. PDL disagrees. Lilly has expressly repudiated the contract by informing PDL that it will not pay PDL royalties that it will be owed. Moreover, Lilly’s purported interpretation of the Agreement to require PDL to have undertaken the humanization of donanemab itself has no good-faith basis in the plain language of the contract.

### C. **Defendant’s Statement of Claims**

Plaintiff’s complaint is deficient for the reasons explained in Defendant’s Memorandum of Law in Support of its Motion to Dismiss (ECF 36). Plaintiff fails to adequately allege that donanemab is a Licensed Product that incorporates “PDL Technical Information” under the Agreement. Instead, the complaint merely parrots the contractual definition of a “Licensed Product” and fails to allege how donanemab fits that definition. Separately, Plaintiff’s anticipatory breach claim fails because a good-faith disagreement about the application of disputed contractual provisions does not constitute an anticipatory breach under California law, which Plaintiff alleges governs the claim. Finally, Plaintiff’s Declaratory Judgment Act claim is not cognizable under that statute.

If Lilly’s motion to dismiss is denied, these claims will fail on the merits because donanemab is not a “Licensed Product” under the Agreement nor does donanemab incorporate Plaintiff’s “Technical Information.” Lilly developed donanemab on its own, using its own information and methods, and PDL has never offered any explanation at all about how donanemab incorporates any part of a PDL antibody or how Lilly used PDL Technical Information. Indeed, Plaintiff does not even contend that it worked on donanemab.

## III. **Pretrial Pleadings and Disclosures**

The parties’ proposed schedule is consistent with the sequencing of this Court’s local rules.

- A. The parties shall serve their Fed. R. Civ. P. 26 initial disclosures on or before July 30, 2024.
- B. Plaintiff shall file preliminary witness and exhibit lists on or before August 6, 2024.
- C. Defendant shall file preliminary witness and exhibit lists on or before August 13, 2024.
- D. All motions for leave to amend the pleadings and/or to join additional parties shall be filed on or before August 27, 2024.
- E. Plaintiff shall serve Defendant (but not file with the Court) a statement of special damages, if any, and make a settlement proposal, on or before August 27, 2024.

Defendant shall serve on the Plaintiff (but not file with the Court) a response thereto within 30 days after receipt of the proposal.

- F. Except where governed by paragraph (G) below, expert witness disclosure deadlines shall conform to the following schedule: Plaintiff shall disclose the name, address, and vita of any expert witness, and shall serve the report required by Fed. R. Civ. P. 26(a)(2) on or before February 25, 2025. Defendant shall disclose the name, address, and vita of any expert witness, and shall serve the report required by Fed. R. Civ. P. 26(a)(2) on or before April 1, 2025.
- G. Notwithstanding the provisions of paragraph (F), above, if a party intends to use expert testimony in connection with a motion for summary judgment to be filed by that party, such expert disclosures must be served on opposing counsel no later than 90 days prior to the dispositive motion deadline. If such expert disclosures are served, the parties shall confer within 7 days to stipulate to a date for responsive disclosures (if any) and completion of expert discovery necessary for efficient resolution of the anticipated motion for summary judgment. The parties shall make good faith efforts to avoid requesting enlargements of the dispositive motions deadline and related briefing deadlines. Any proposed modifications of the CMP deadlines or briefing schedule must be approved by the Court.
- H. Any party who wishes to limit or preclude expert testimony at trial shall file any such objections on or before 120 days before trial. Any party who wishes to preclude expert witness testimony at the summary judgment stage shall file any such objections with their responsive brief within the briefing schedule established by S.D. Ind. L.R. 56-1.
- I. All parties shall file and serve their final witness and exhibit lists on or before 60 days before trial. This list should reflect the specific potential witnesses the party may call at trial. It is not sufficient for a party to simply incorporate by reference “any witness listed in discovery” or such general statements. The list of final witnesses shall include a brief synopsis of the expected testimony.
- J. Any party who believes that bifurcation of discovery and/or trial is appropriate with respect to any issue or claim shall notify the Court as soon as practicable.
- K. Discovery of electronically stored information (“ESI”). If either party is seeking the production of a substantial volume of ESI, then complete the [ESI Supplement to the Report of the Parties’ Planning Meeting](#) (also available in MS Word on the court’s website at <http://www.ind.uscourts.gov/case-management-plans>).

If the parties believe that a substantial volume of ESI will not be produced in the case, the parties should include herein a brief description of the information anticipated to be sought in discovery in the case and include (1) the parties’ agreement regarding the format in which ESI will be produced (including whether the production will include metadata), (2) a description of any other issues the

parties believe may be relevant to discovery in the case, and (3) either the following claw-back provision or the language of any alternative provision being proposed:

In the event that a document protected by the attorney-client privilege, the attorney work product doctrine or other applicable privilege or protection is unintentionally produced by any party to this proceeding, the producing party may request that the document be returned. In the event that such a request is made, all parties to the litigation and their counsel shall promptly return all copies of the document in their possession, custody, or control to the producing party and shall not retain or make any copies of the document or any documents derived from such document. The producing party shall promptly identify the returned document on a privilege log. The unintentional disclosure of a privileged or otherwise protected document shall not constitute a waiver of the privilege or protection with respect to that document or any other documents involving the same or similar subject matter.

#### **IV. Discovery<sup>1</sup> and Dispositive Motions**

Due to the time and expense involved in conducting expert witness depositions and other discovery, as well as preparing and resolving dispositive motions, the Court requires counsel to use the CMP as an opportunity to seriously explore whether this case is appropriate for such motions (specifically including motions for summary judgment), whether expert witnesses will be needed, and how long discovery should continue. To this end, counsel must select the track set forth below that they believe best suits this case. If the parties are unable to agree on a track, the parties must: (1) state this fact in the CMP where indicated below; (2) indicate which track each counsel believes is most appropriate; and (3) provide a brief statement supporting the reasons for the track each counsel believes is most appropriate. If the parties are unable to agree on a track, the Court will pick the track it finds most appropriate, based upon the contents of the CMP or, if necessary, after receiving additional input at an initial pretrial conference.

- A. Does any party believe that this case may be appropriate for summary judgment or other dispositive motion?

**Plaintiff's Response:** PDL anticipates the likelihood of filing a dispositive motion subject to additional information learned in discovery.

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<sup>1</sup> The term "completed," as used in Section IV.C, means that counsel must serve their discovery requests in sufficient time to receive responses before this deadline. Counsel may not serve discovery requests within the 30-day period before this deadline unless they seek leave of Court to serve a belated request and show good cause for the same. In such event, the proposed belated discovery request shall be filed with the motion, and the opposing party will receive it with service of the motion but need not respond to the same until such time as the Court grants the motion.

**Defendant's Response:** If the Court denies Defendant's Motion to Dismiss (ECF 35), Defendant anticipates that it will file a motion for summary judgment on Plaintiff's claims because the undisputed facts will show that donanemab is not a royalty-bearing product under the Agreement. Donanemab is not a "Licensed Product," nor does it incorporate "PDL Technical Information."

B. On or before 7 days after the non-expert discovery deadline referenced in Paragraph IV.C below, and consistent with the certification provisions of Fed. R. Civ. P. 11(b), the party with the burden of proof shall file a statement of the claims or defenses it intends to prove at trial, stating specifically the legal theories upon which the claims or defenses are based.

C. Track 2

**Plaintiff's Position:** Dispositive motions are expected and shall be filed by March 27, 2025; non-expert witness discovery and discovery relating to liability issues shall be completed by January 27, 2025; expert witness discovery and discovery relating to damages shall be completed by June 27, 2025. All remaining discovery shall be completed by no later than July 25, 2025.

**Defendant's Position:** It is premature to set dispositive motion deadlines, given there is a pending motion to dismiss PDL's complaint with prejudice. Accordingly, Lilly proposes deadlines keyed off a denial (or denial after an amendment) if one occurs. Dispositive motions are expected and shall be filed by eight months after a denial (if any) of Lilly's motion to dismiss; non-expert witness discovery and discovery relating to liability issues shall be completed by seven months after a denial (if any) of Lilly's motion to dismiss; expert witness discovery and discovery relating to damages shall be completed by twelve months after a denial (if any) of Lilly's motion to dismiss. All remaining discovery shall be completed by no later than thirteen months after a denial (if any) of Lilly's motion to dismiss.

Absent leave of Court, and for good cause shown, all issues raised on summary judgment under Fed. R. Civ. P. 56 must be raised by a party in a single motion.

## V. **Pre-Trial/Settlement Conferences**

At any time, any party may call the Judge's Staff to request a conference, or the Court may *sua sponte* schedule a conference at any time. The presumptive time for a settlement conference is no later than 30 days before the close of non-expert discovery. The parties are encouraged to request an earlier date if they believe the assistance of the Magistrate Judge would be helpful in achieving settlement. The parties recommend a settlement conference 90 days after the Trigger Date.

## VI. **Trial Date**

**Plaintiff's Position:** PDL requests a trial date in October 2025. The trial is by jury and is anticipated to take 5 days.



**Defendant's Position:** If Lilly's motion to dismiss is denied, the Court will determine a trial date. The trial is by jury and is anticipated to take 5 days.

**VII. Referral to Magistrate Judge**

- A. **Case.** At this time, all parties do not consent to refer this matter to the currently assigned Magistrate Judge pursuant to 28 U.S.C. 636(c) and Fed. R. Civ. P. 73 for all further proceedings including trial.
- B. **Motions.** The parties do not consent to having the assigned Magistrate Judge rule on motions ordinarily handled by the District Judge, such as motions to dismiss, for summary judgment, or for remand. If all parties consent, they should file a joint stipulation to that effect. Partial consents are subject to the approval of the presiding district judge.

**VIII. Required Pre-Trial Preparation**

- A. **TWO WEEKS BEFORE THE FINAL PRETRIAL CONFERENCE, the parties shall:**
  - 1. File a list of trial witnesses, by name, who are actually expected to be called to testify at trial. This list may not include any witnesses not on a party's final witness list filed pursuant to Section III.I.
  - 2. Number in sequential order all exhibits, including graphs, charts and the like, that will be used during the trial. Provide the Court with a list of these exhibits, including a description of each exhibit and the identifying designation. Make the original exhibits available for inspection by opposing counsel. Stipulations as to the authenticity and admissibility of exhibits are encouraged to the greatest extent possible.
  - 3. Submit all stipulations of facts in writing to the Court. Stipulations are always encouraged so that at trial, counsel can concentrate on relevant contested facts.
  - 4. A party who intends to offer any depositions into evidence during the party's case in chief shall prepare and file with the Court and copy to all opposing parties either:
    - a. brief written summaries of the relevant facts in the depositions that will be offered. (Because such a summary will be used in lieu of the actual deposition testimony to eliminate time reading depositions in a question and answer format, this is strongly encouraged.); or
    - b. if a summary is inappropriate, a document which lists the portions of the deposition(s), including the specific page and line numbers, that will be read, or, in the event of a video-taped deposition, the



portions of the deposition that will be played, designated specifically by counter-numbers.

5. Provide all other parties and the Court with any trial briefs and motions in limine, along with all proposed jury instructions, voir dire questions, and areas of inquiry for voir dire (or, if the trial is to the Court, with proposed findings of fact and conclusions of law).
6. Notify the Court and opposing counsel of the anticipated use of any evidence presentation equipment.

**B. ONE WEEK BEFORE THE FINAL PRETRIAL CONFERENCE, the parties shall:**

1. Notify opposing counsel in writing of any objections to the proposed exhibits. If the parties desire a ruling on the objection prior to trial, a motion should be filed noting the objection and a description and designation of the exhibit, the basis of the objection, and the legal authorities supporting the objection.
2. If a party has an objection to the deposition summary or to a designated portion of a deposition that will be offered at trial, or if a party intends to offer additional portions at trial in response to the opponent's designation, and the parties desire a ruling on the objection prior to trial, the party shall submit the objections and counter summaries or designations to the Court in writing. Any objections shall be made in the same manner as for proposed exhibits. However, in the case of objections to video-taped depositions, the objections shall be brought to the Court's immediate attention to allow adequate time for editing of the deposition prior to trial.
3. File objections to any motions in limine, proposed instructions, and voir dire questions submitted by the opposing parties.
4. Notify the Court and opposing counsel of requests for separation of witnesses at trial.

**IX. Other Matters**

N/A

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	PARTIES APPEARED IN PERSON/BY COUNSEL ON _____ FOR A PRETRIAL/STATUS CONFERENCE.
	APPROVED AS SUBMITTED.
	APPROVED AS AMENDED.
	APPROVED AS AMENDED PER SEPARATE ORDER.
	APPROVED, BUT ALL OF THE FOREGOING DEADLINES ARE SHORTENED/LENGTHENED BY _____ MONTHS.
	APPROVED, BUT THE DEADLINES SET IN SECTION(S) _____ OF THE PLAN IS/ARE SHORTENED/LENGTHENED BY _____ MONTHS.
	THIS MATTER IS SET FOR TRIAL BY _____ ON _____ . FINAL PRETRIAL CONFERENCE IS SCHEDULED FOR _____ AT _____ .M., ROOM _____.
	<p>A SETTLEMENT/STATUS CONFERENCE IS SET IN THIS CASE FOR _____ AT _____ .M. COUNSEL SHALL APPEAR:</p> <p>_____ IN PERSON IN ROOM _____; OR</p> <p>_____ BY TELEPHONE, WITH COUNSEL FOR INITIATING THE CALL TO ALL OTHER PARTIES AND ADDING THE COURT JUDGE AT (____)</p> <p>_____ ; OR</p> <p>_____ BY TELEPHONE, WITH COUNSEL CALLING THE JUDGE'S STAFF AT (____)</p> <p>_____ ;</p>
	DISPOSITIVE MOTIONS SHALL BE FILED NO LATER THAN _____

Upon approval, this Plan constitutes an Order of the Court. Failure to comply with an Order of the Court may result in sanctions for contempt, or as provided under Fed. R. Civ. P. 16-1(f), to and including dismissal or default.

**APPROVED AND SO ORDERED.**